IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NOVARTIS PHARMACEUTICALS CORPORATION,

Plaintiff,

v.

HEC PHARM CO., LTD., et al.,

Defendants.

C.A. 20-133-JLH (Consolidated)

[redacted]

PUBLIC VERSION FILED: September 12, 2025

NOVARTIS'S BRIEF IN OPPOSITION TO DEFENDANTS' MOTION FOR SUMMARY JUDGMENT ON OBVIOUSNESS AND *DAUBERT* MOTION TO EXCLUDE THE OPINIONS OF DR. STEINMAN

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TABLE OF ABBREVIATIONS

Abbreviation	Document
’179 Patent	U.S. Patent No. 10,543,179 (D.I. 386-1, Ex. G)
07/17/2025 Vellturo Dep. Tr.	Deposition Transcript of Christopher A. Vellturo, Ph.D., dated July 17, 2025 (D.I. 386-2, Ex. V)
1/31/2025 Harris Dep. Tr.	Deposition Transcript of Joshua Harris, dated Jan. 31, 2025, 2025 (D.I. 392-1, Ex. 12)
2/11/2025 Baeringer Dep. Tr.	Deposition Transcript of Ira Baeringer, dated Feb. 11, 2025 (D.I. 392-1, Ex. 11)
7/10/2025 Berger Dep. Tr.	Deposition Transcript of Joseph Berger, dated July 10, 2025 (D.I. 386-1, Ex. Q)
7/14/2025 Pleasure Dep. Tr.	Deposition Transcript of Samuel Pleasure, dated July 14, 2025 (D.I. 386-1, Ex. K)
Berger Op. Rpt.	[Corrected] First Expert Report of Joseph R. Berger, M.D. regarding Infringement of U.S. Patent No. 10,543,179, dated April 16, 2025 (D.I. 386-1, Ex. O)
Defendants	HEC Pharm Co., Ltd., HEC Pharm Usa Inc. (“HEC”), Sunshine Lake Pharma Co., Ltd. (“Sunshine”), CANDA HEC-1, LLC (“CANDA”), and Rising Pharma Holdings, Inc. d/b/a Rising Pharmaceuticals, Inc. (“Rising”)
DMT	Disease-modifying therapy
Ex.	Exhibit to the Declaration of Robert Trenchard, filed concurrently herewith
FRE	Federal Rules of Evidence
Lublin Op. Rpt.	First Expert Report of Fred D. Lublin, M.D., dated April 15, 2025 (D.I. 386-1, Ex. L)
Masztak Reb. Rpt.	Rebuttal Expert Report of Anthony M. Masztak, dated May 20, 2025 (D.I. 379-1, Ex. 1)
MTPC	Mitsubishi Tanabe Pharma Corporation
Novartis or Plaintiff	Novartis Pharmaceuticals Corporation
Novartis’s Principal Brief in Appeal No. 2021-1070	*Novartis Pharms. Corp. v. Accord Healthcare Inc. et al.*, Appeal No. 2021-1070, D.I. 22 (Fed. Cir. March 9, 2021) (Ex. 3)
Pleasure Reb. Rpt.	Rebuttal Expert Report Of Samuel Pleasure, M.D., Ph.D. On Non-Infringement Of U.S. Patent No. 10,543,179 (D.I. 386-1, Ex. J)
RRMS	Relapse-remitting multiple sclerosis
S1P	Sphingosine-1-phosphate
SFO	Plaintiff’s Statement of Facts in Opposition to Defendants’ Motion for Summary Judgment and *Daubert* Preclusion on Infringement and Damages Issues, filed concurrently herewith
Side-by-Side Comparison of June 2024 Gilenya® Label and October	Defendants’ ANDA 207939 Annex 1 Side-by-side comparison of proposed labeling and last submitted labeling (HECFINGO00126347) (D.I. 392-2–392-4, Ex. 23)

Abbreviation	Document
2024 Defendants' Label	
Steinman Reb. Rpt.	First Expert Report of Lawrence Steinman, M.D. regarding Validity of U.S. Patent No. 10,543,179, dated May 20, 2025 (D.I. 386-1, Ex. S)
Vellturo Op. Rpt.	Expert Report of Christopher A. Vellturo, Ph.D., dated April 15, 2025 (D.I. 386-2, Ex. T)
Vellturo Reply Rpt.	Reply Expert Report of Christopher A. Vellturo, Ph.D., dated June 17, 2025 (D.I. 386-2, Ex. U)
VZV	Varicella zoster virus

PRELIMINARY STATEMENT

Dr. Larry Steinman submits a report for Novartis rebutting Defendants' contention that U.S. Patent No. 10,543,179 (the '179 Patent) is invalid as obvious. Dr. Steinman is an eminent scientist—a member of the National Academy of Sciences—and a medical doctor specializing in multiple sclerosis (MS). He shows how the '179 Patent inventors developed a novel vaccination and dosing protocol for protecting patients on the MS medicine Gilenya from infection by varicella zoster virus (VZV). As Dr. Steinman explains, many neurologists at the time (and today) feared that live vaccines like the one for VZV could worsen MS. But the inventors' work showed that a vaccine plus a low dose struck the appropriate balance of risk and reward. This discovery—the output of years of work stemming from Novartis's clinical trials—led to the '179 Patent.

Defendants, however, argue Dr. Steinman's report should be struck under *Daubert* because he allegedly relies on the path of the invention to show non-obviousness. On this and other bases, Defendants say summary judgment on obviousness should be entered. Defendants are wrong.

Dr. Steinman's opinion does not depend on the inventors' path. He reviews the literature and concludes that a person of skill would have had neither a motivation to combine nor a reasonable expectation of success. At that time, no public data linked Gilenya to VZV infection; neurologists' aversion to live vaccines taught away from the invention; and Gilenya's mechanism of action caused concern a vaccine would not work. At most, a clinical trial death had raised the question of a possible connection between Gilenya's active ingredient fingolimod and VZV. However, other factors—the patient had taken a high dose and been on steroids, a known VZV risk factor—obscured fingolimod's role. Dr. Steinman reached this conclusion based on the literature and certain objective facts about the inventors' work, including that only the inventors established a link between fingolimod and VZV and then showed a vaccine would remain effective. These are all typical uses of objective evidence of nonobviousness.

Defendants complain that Dr. Steinman cites non-public documents, but this critique again is off-base: Dr. Steinman analyzes whether a person of skill in 2010 would have considered the invention obvious based on public information. Non-public information is used only to spotlight what the public record was missing, and to address objective indicia of non-obviousness. And while Defendants assert Dr. Steinman applied too high a standard to assess reasonable expectation of success, that too is incorrect. Dr. Steinman assessed whether a person of skill in 2010 would have thought a vaccination protocol plus a lower dose would have had a "reasonable" chance of reducing the drug's risks, and he concludes the answer would have been "no." Without the inventors' work, a neurologist would have thought the risk-reward benefit tipped against a vaccine protocol. Plus, a neurologist would have been concerned that fingolimod's effect on the immune system—the very thing thought to make fingolimod an effective medicine—would neuter the effect of any vaccine. Defendants may disagree with Dr. Steinman's opinions, but that is an issue for cross-examination at trial, not one that supports exclusion.

These sound foundations for Dr. Steinman's views easily satisfy FRE 702, and Defendants' combined *Daubert* and summary judgment motion should be denied.

FACTS

The facts here are in the accompanying concise statement of facts in opposition (CSFO), concise statement of facts in support (CSOF), and the August 28, 2025 Declaration of Robert W. Trenchard and exhibits thereto ("Exs.").

The Asserted Patent

Novartis sued Defendants for infringing the '179 Patent based on Defendants' copy of Gilenya. (D.I. 1; 367.) Novartis filed the application leading to the '179 Patent in September 2010. (D.I. 386-1, Ex. G ('179 Patent) at 1; Ex. S (Steinman Reb. Rpt.) ¶ 160.) The Patent claims a protocol for protecting patients on fingolimod from VZV. (*Id.*, Ex. G at Cls. 1–4.) The protocol

entails testing patients for VZV immunity; if no immunity is found, inoculating the patient against VZV; and then prescribing a 0.5 mg daily dose of fingolimod. (*Id.*)

MS is an autoimmune disease in which the body's lymphocytes (white blood cells) attack the central nervous system. (*Id.* at 1:4–12, 57–60; Ex. S (Steinman Reb. Rpt.) ¶¶ 25–37.) The relapsing-remitting form of the disease—called "RRMS," the most common form—manifests with periods of attacks (called "relapses") followed by periods of remission. (*Id.*, Ex. S ¶¶ 27–29.) Fingolimod—the first in a then-new class of drugs called S1P receptor modulators—works by sequestering lymphocytes in lymph nodes. That inhibits lymphocytes from attacking the central nervous system and thereby exacerbating multiple sclerosis. (*Id.*, Ex. G ('179 Patent) at 1:53–60.) However, this mechanism carries the risk of increased infections, including from VZV. (*Id.* at 8:47, 10:47–49.) To ameliorate this risk, the patented protocol calls for the patient to "be tested for history of infections, e.g., viral infection, in particular chickenpox. In case the searched serology is negative, the patient may be vaccinated, e.g. against [VZV.]" (*Id.* at 10:59–63.)

Defendants argue the '179 Patent is obvious. They submit reports from Dr. Samuel Pleasure, a University of California San Francisco neurologist and MS doctor. (*See generally*, D.I. 392-1, Ex. 2 (Pleasure Op. Rpt.); Ex, 4 (Pleasure Reply Rpt.).) Dr. Pleasure argues that the VZV protocol would have been self-evident because in September 2010, publications had disclosed the 2008 death from VZV in the Gilenya clinical trials. (*See, e.g.*, D.I. 392-1, Ex. 2 ¶¶ 165–347.) That, plus public knowledge about the VZV vaccine, would have led a neurologist to conclude that vaccination was obvious. (*Id.*)

Dr. Steinman's Report

Dr. Steinman submits a report in opposition. Dr. Steinman is Professor of Neurology and Neurological Sciences and Pediatrics at the Stanford University School of Medicine. (D.I. 386-1,

Ex. S (Steinman Reb. Rpt.) ¶¶ 11–23.) He has authored or co-authored over 600 publications, cared for about 4,000–5,000 MS patients, and advised multiple biotech companies in his over 40-year career. His "groundbreaking discoveries on the molecular basis for relapsing multiple sclerosis" were cited for his induction into the National Academy of Sciences. (*Id.*)

Dr. Steinman describes the features of MS and the state of the art in 2010. At that time, "there was a strong caution in the art against vaccinating MS patients with live VZV vaccines." (*Id.* ¶ 52.) "[M]ultiple studies had shown that 'infection can trigger a[n] [MS] relapse and it has been observed that there is increased incidence of clinical relapse in MS patients associated with infections.'" (*Id.* ¶ 41.) A series of publications specifically postulated a link between MS relapses and VZV infection based on serological data. (*Id.* ¶¶ 43–46.) The only available VZV vaccine in 2010 (and today) was a live attenuated virus. It triggers a low-grade infection. (*Id.* ¶¶ 49–50.) Accordingly, physicians were and remain concerned about the potential for VZV to trigger RRMS attacks. (*Id.* ¶ 51.) As Dr. Steinman shows, every RRMS attack poses a substantial risk of permanent disability. (*Id.* ¶ 29.) Thus, without sufficient justification, neurologists were hesitant to administer a live VZV vaccine to RRMS patients. (*Id.* ¶¶ 52, 72–73.)

Nothing in the prior art provided that justification, including the four references Dr. Pleasure cites: Kappos NEJM 2010, Cohen 2010, Berger 2009, and Harpaz 2008. Berger 2009 describes how, in May 2008, a female patient enrolled in one fingolimod clinical trial on a 1.25 mg dose died of VZV complications. (*Id.* ¶ 105.) Dr. Pleasure admits this "singular event" did not "allow you to draw statistical inference." (D.I. 386-1, Ex. K (7/14/2025 Pleasure Dep. Tr.) at 219:7–11.) That was especially so because the patient was also on steroids, a known risk factor for VZV infection. (D.I., 386-1, Ex. S (Steinman Reb. Rpt.) ¶¶ 62, 109–110, 163, 215, 223, 228–229, 237; Ex. K at 192:23–25 ("[c]orticosteroids alone can be a risk factor" for VZV).) As such,

nothing suggested "that fingolimod increases the risk of VZV infection." (*Id.*, Ex. S ¶ 215.) Contemporary publications noted these issues, including Garber 2008 and Berger 2009, which flagged "high-dose steroids . . . potentially contributing to the outcome." (*Id.*)

The prior art also did not teach whether the VZV vaccine would elicit a meaningful immune response in fingolimod recipients. (*Id.* ¶ 223.) As Dr. Steinman explains, even papers Dr. Pleasure cites note that fingolimod's mechanism of action might neutralize the effect of any vaccination. For example, Berger 2009 says "the safety of vaccination in the setting of these immunomodulatory drugs needs to be established" and "an attenuated response to certain vaccines may be observed in this MS population." (*Id.*) Consistent with the state of the art, Novartis internal records indicate a wide diversity of opinion from eminent neurologists on whether VZV vaccination would be advisable in VZV seronegative RRMS patients. (*See, e.g.*, *id.* ¶ 121; D.I. 393-1, Ex. B (7/18/2025 Steinman Dep. Tr.) at 54:7–56:18.)

The '179 Patent inventors were first to discover that others' skepticism was misplaced. The inventors figured out that fingolimod use correlated with an increased VZV risk and that fingolimod would not render vaccines ineffective. The results of this research were not published until the Arvin 2015 and Boulton 2012 papers, respectively. (D.I., 386-1, Ex. S (Steinman Reb. Rpt.) ¶¶ 136–143, 214–225.)

Dr. Steinman's Deposition

Dr. Steinman testified in deposition in line with the foregoing. He explained that the prior art did not reveal "that Novartis knew"—a "compelling" study of the risk-benefit balance from vaccination. (D.I. 393-1, Ex. B at 162:4–25.) Internal analysis from inventor Dr. Ana de Vera showed a correlation between fingolimod and VZV infection. (*Id.* at 208:18–209:6, 203:17–205:16, 205:16–206:9, 207:7–208:16, 96:20–97:15.)

As Dr. Steinman explained, these kinds of nonpublic data illustrate what the public literature did not disclose. (*Id.*; *see also id.* at 197:22–198:11 ("The question of obviousness has to do with whether you know or whether it's known to the public . . . and it wasn't.").) For instance, outside doctors in a Novartis "Steering Committee" expressed a diversity of views on the wisdom of vaccination. (*Id.* at 104:12–105:7, 52:25–54:3, 68:15–69:18 ("it's not conceivable to me that a POSA would state that it's obvious to vaccinate if the experts had that kind of diversity").) There is no evidence in the prior art to suggest that persons of ordinary skill would have had more confidence on this issue, or a reasonable expectation of success.

Additional testimony from Dr. Steinman confirms the prior art did not reveal if fingolimod increased VZV risk or if a vaccine would even be effective. (*Id.* at 195:5–196:16 (Cohen 2010 does not disclose "proprietary information"), 197:22–198:11 ("The question of obviousness has to do with whether you know or whether it's known to the public, including oneself, all of the available information, and it wasn't. Some of the most vital information was proprietary."), 179:8–180:11 ("Even if you immunized successfully, would the effect wear out because you put the person on the immune suppressive drug[?]").) Thus, a person of skill "would need to know a lot more [than what was in the prior art] before making that decision [of what dose to administer a patient]" in the context of the '179 Patent, and that "[a] POSA only would know what was in the New England Journal paper [(Cohen)] and I don't think that would be sufficient." (*Id.* at 41:20–42:16, 43:2–17.)

ARGUMENT

Defendants' *Daubert* and summary judgment motions targeted at Dr. Steinman have no merit. Dr. Steinman's work easily meets the standards for relevance and reliability in FRE 702 and *Daubert*. *EcoFactor, Inc. v. Google LLC*, 137 F.4th 1333, 1339 (Fed. Cir. 2025) (expert testimony must be "not only relevant, but reliable") (quoting *Daubert v. Merrell Dow Pharm. Inc.*,

509 U.S. 579 (1993)) (cleaned up). Defendants' summary judgment motion asks the Court to ignore the extensive factual disputes that remain regarding validity issues on which they have the burden of proof. Both motions should be denied.

I. Dr. Steinman's Analysis Easily Satisfies FRE 702 and *Daubert*

It has long been the law that "evidence rising out of the so-called 'secondary considerations' must always when present be considered en route to a determination of obviousness." *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1538–39 (Fed. Cir. 1983); *see also In re Cyclobenzaprine Hydrochloride Extended-Release Capsule Pat. Litig.*, 676 F.3d 1063, 1075 (Fed. Cir. 2012) (requiring that all evidence relevant to obviousness or nonobviousness, including secondary considerations, be considered collectively). This includes the inventors' private documents and analyses to show motivation to combine, reasonable expectation of success, unexpected results, teaching away, skepticism of others, and the like.

For instance, in *Neptune Generics, LLC v. Eli Lilly & Co.*, 921 F.3d 1372, 1378 (Fed. Cir. 2019), the Federal Circuit upheld a Patent Office finding that non-prior art communications from the FDA's medical officer to the patentee supported non-obviousness. And in *In re Copaxone*, 906 F.3d 1013, 1029–30 (Fed. Cir. 2018), the Federal Circuit upheld the district court's reliance on non-prior art FDA communication not as "invalidating prior art, but instead as evidence of a POSITA's motivations and expectations when reading the prior art at the time of the invention." Many other examples are in the law. *See, e.g.*, *Yeda Rsch. v. Mylan Pharms. Inc.*, 906 F.3d 1031, 1041 (Fed. Cir. 2018) (non-prior art reference was "probative of the fact that those skilled in the art were motivated to investigate dosing regimens of [the invention] with fewer injections to improve patient compliance") (internal citations omitted); *Medtronic Vascular Inc. v. Abbott Cardiovascular Sys., Inc.*, 614 F. Supp. 2d 1006, 1028–29 (N.D. Cal. 2009), *amended on*

reconsideration, 2009 WL 1764749 (N.D. Cal. June 22, 2009) ("[E]ven if [defendants' 'secret' and 'internal' work] do not constitute prior art that is admissible for purposes of . . . § 103, the references are nonetheless admissible for purposes of demonstrating the ordinary skill in the art with respect to obviousness, and as evidence going to secondary considerations of obviousness.").

The cases Defendants cite are not to the contrary. *Life Techs., Inc. v. Clontech Lab'ys, Inc.*, 224 F.3d 1320 (Fed. Cir. 2000) (D.I. 383-0 at 4) merely holds that "information regarding the subjective motivations of inventors is not material" for inequitable conduct. *Id.* at 1325. *Exelixis, Inc. v. MSN Lab'ys Priv. Ltd.*, 2022 WL 6697634 (D. Del. Apr. 20, 2022) (D.I. 383-0 at 9) precluded defendants' use of evidence of "path taken by the inventors" in their obviousness argument, rather than to rebut it. *Id.* at *6. Similarly, *Millennium Pharms., Inc. v. Sandoz Inc.*, 862 F.3d 1356, (Fed. Cir. 2017) (D.I. 383-0 at 4) merely prohibits finding (not rebutting) obviousness based on evidence of what the inventors "intended." *Id.* at 1367. Dr. Steinman is not offering opinions on the mindset of the inventors, and his reliance on non-public information at the time of the invention has nothing to do with what the inventors intended. Instead, he relies on non-public materials as part of his opinion of non-obviousness because they provide objective indicia relating to what others in the field were thinking (or not thinking) at the relevant time.

A. Dr. Steinman Properly Analyzes the Evidence to Rebut Dr. Pleasure's Obviousness Opinion

Defendants claim that Dr. Steinman's rebuttal to Dr. Pleasure improperly depends on "the path of the '179 patent's inventors, including the proprietary studies they undertook and the internal documents and discussion with Novartis's steering committee experts to which they had access." (D.I. 383-0 at 4–9.) To the contrary, it was Defendants' own expert, Dr. Pleasure, that first relied on information not known to a person of skill for his analysis.

For example, Dr. Pleasure's Opening Report cites multiple documents not in the prior art. (*See, e.g.*, D.I. 392-1, Ex. 2 (Pleasure Op. Rpt.) ¶¶ 205 (citing a Novartis Q&A with FTY trial investigators), 225 (citing in support of his opinions a confidential July 11, 2008 Novartis consultation with infectious disease experts), 250 (citing an internal June 6, 2008 Email from Dr. Hodgkinson to others at Novartis), 252–256 (citing internal correspondence with trial investigators and Steering Committee members).) Defendants cannot rely on these documents in support of their *prima facie* obviousness case and then cry foul when Dr. Steinman addresses those and other similar documents in his rebuttal opinion.

More substantively, Dr. Steinman merely relied on these non-public materials to show unexpected results, a typical use for such evidence. *See, e.g.*, *W.R. Grace & Co.-Conn. v. Intercat, Inc.*, 7 F. Supp. 2d 425, 464, 466 (D. Del. 1997), *aff'd sub nom. W.R. Grace & Co. v. Intercat, Inc.*, 155 F.3d 572 (Fed. Cir. 1998) (inventors' internal tests showing "unanticipated results in the initial activity of the spinel composition" from its novel sulfur reduction additive were "compelling evidence of non-obviousness"). Despite Dr. Steinman's repeated explanations in his report and at deposition that a neurologist would not have been aware of "any known statistical association between the risk of VZV from fingolimod" in the prior art, and nothing in the prior art "even theoretically suggest[ed] that fingolimod increases the risk of VZV Infection," (D.I. 386-1, Ex. S (Steinman Reb. Rpt.) ¶ 215; D.I. 393-1, Ex. B (7/18/2025 Steinman Dep. Tr.) 126:4–19), Dr. Pleasure provides only conclusory opinions on obviousness based on "common sense." (D.I. 386-1, Ex. K (7/14/2025 Pleasure Dep. Tr.) 216:10–19). But "'common sense'—whether to supply a motivation to combine or a missing limitation—cannot be used as a wholesale substitute for reasoned analysis and evidentiary support, especially when dealing with a limitation missing from the prior art references specified." *Arendi S.A.R.L. v. Apple Inc.*, 832 F.3d 1355, 1362 (Fed. Cir.

2016); *see also Janssen Pharms., Inc. v. Mylan Lab'ys Ltd.*, 2023 WL 3605733, at *20–21 (D.N.J. May 23, 2023) ("'common sense' cannot be used to lead a POSA to develop missing elements of the claim because the missing elements are not 'unusually simple' or the technology at issue 'particularly straightforward,'" such as in "the medical arts").

Indeed, at his deposition, Dr. Steinman explained the elements of the claimed invention are not found in the prior art and thus were unexpected to a person of skill, testifying that "the question was are the claims obvious . . . [i]t's based on data that are pretty compelling . . . [a]nd a POSA would not have had access to that . . . the POSA would not have known that Novartis knew. (D.I. 393-1, Ex. B (7/18/2025 Steinman Dep. Tr.) at 162:4–25; *see also id.* at 205:16–206:9 ("how much steroid was used by the person who died [in the TRANSFORMS trial as reported in Dr. Pleasure's asserted prior art] was not in the public domain").) Consistent with Dr. Steinman's opinion that a person of skill would not have known whether fingolimod actually increased VZV infection rate, Dr. Pleasure even admitted that the "singular event" of the clinical trial death "doesn't allow you to draw statistical inference." (D.I. 386-1, Ex. K (7/14/2025 Pleasure Dep. Tr.) at 219:7–11.)

Defendants next argue that "Dr. Steinman repeatedly emphasized his reliance on the confidential 2008 opinions of Novartis's steering committee members, who had access to confidential Novartis information not available to a POSA." (D.I. 383-0 at 5–7.) However, Dr. Steinman's testimony was once again discussing that a neurologist would not have expected a benefit from vaccinating VZV seronegative individuals prior to treatment with 0.5 mg of fingolimod. Indeed, during this line of questioning, Dr. Steinman was asked, and once again confirmed, that this link was proprietary as of September 2010, testifying that "certainly in the [Cohen prior art] paper he doesn't go into it, but there was already the establishment of a collection of data about what dose of FTY was more risky for the VZV complication, and that would have

been the 1.25. So that's not in the Cohen paper . . . [a]nd Cohen does not go into that discussing the two deaths. . . [t]hat's not in the Cohen paper because that was proprietary information." (D.I. 393-1, Ex. B (7/18/2025 Steinman Dep. Tr.) at 195:5–196:16; *see also id.* at 150:21–152:1 ("I would point to in the case of not knowing that 1.25 was a higher risk than .5 for having shingles, so a POSA wouldn't know that. That's very important to know. Could you vaccinate a person and then put them on fingolimod?"), 197:22–198:11 ("Some of the most vital information was proprietary").)

As shown above, Dr. Steinman's analysis does not depend "on the inventor's path." His testimony properly responds to Dr. Pleasure's opinions and explains that the prior did not disclose the information a person of skill needed to have been motivated to combine the prior art references with a reasonable expectation of success. Such testimony and opinions are squarely within the realm of accepted expert opinion. *See, e.g.*, *W.R. Grace*, 7 F. Supp. 2d at 464, 466.

Defendants argue also that "the emphasis that Dr. Steinman placed on the inventors' paths is evidenced by his Report." (D.I. 383-0 at 7–9.) But they largely cite to portions of Dr. Steinman's report addressing issues besides obviousness, such as background sections describing how the '179 Patent invention works and how it was discovered. (*Id.* (citing a "Facts" section, a "FDA Review of Fingolimod" section, and "The Invention of the '179 Patent" section).") In the few instances that do address obviousness, each paragraph rebuts Dr. Pleasure's opinions and documents cited therein by describing how certain claim limitations or motivations to vaccinate were not present in the prior art. (*See* D.I. 386-1, Ex. S (Steinman Reb. Rpt.) ¶¶ 215–216 (discussing no publicly available art disclosed a statistically significant causative connection between VZV incidence and fingolimod treatment), 223 (explaining it was the inventors' analysis of pooled data that answered unresolved questions in Dr. Pleasure's cited prior art regarding the risk-benefit analysis to

vaccinate RRMS patients against VZV prior to fingolimod therapy), 228 (explaining that a POSA would not have been motivated to vaccinate patients based on the public reporting on the TRANSFORMS trial as of September 2010), 231 (rebutting Dr. Pleasure's erroneous assertions that Novartis adopted a VZV vaccination protocol in response to Advisory Board members' recommendations), 238 (rebutting Dr. Pleasure's reliance on the Advisory Board's responses in support of his opinion that a POSA would be motivated to vaccinate RRMS patients prior to fingolimod treatment and explaining that the Board's general preference was not to vaccinate RRMS patients with a live vaccine without good reason), 242 (explaining the Steering Committee documents cited by Dr. Pleasure actually reflected the "well-known risk that live attenuated vaccines may reactive to infect an immunocompromised host" as reflected in several prior art documents), 244 (discussing the asserted prior art's "absence of motivation to vaccinate RRMS patients against VZV"), 246 (rebutting Dr. Pleasure's alleged motivation to vaccinate RRMS patients by explaining that "the first normative data on the effect of fingolimod on immune response" in the literature did not appear until after the priority date and would not have been known by a POSA), 249 (rebutting Dr. Pleasure's alleged reasonable expectation of success in vaccinating RRMS patients by explaining that a POSA would not have been aware of that the VZV vaccination prior to fingolimod administration would be successful in reducing the risks associated with VZV infection until after Novartis's work became publicly available after September 2010).)

B. Dr. Steinman Offered Proper Rebuttal Opinions Regarding Dose Selection

Defendants allege Dr. Steinman's opinion is that the '179 Patent could "only be obvious if a POSA could determine that this was the 'optimal' dosage." (D.I. 383-0 at 10–12.) Defendants needlessly quibble over the word "optimal" and ignore the context for the cited testimony.

This testimony in the context merely rebutted Dr. Pleasure's assertion that it would have been obvious to vaccinate a patient for VZV before beginning them on a 0.5 mg dosage of fingolimod. Dr. Steinman testified that a person of skill would "need to know a lot more [than what was in the prior art] before making that decision [of what dose to administer a patient]" in the context of the '179 Patent and that "[a] POSA only would know what was in the New England Journal paper [(Cohen)] and I don't think that would be sufficient." (D.I. 393-1, Ex. B (7/18/2025 Steinman Dep. Tr.) at 41:20–42:16, 43:2–17.) Dr. Steinman further explained elsewhere in the deposition (not cited by Defendants) that Dr. Pleasure's prior art did not teach a person of skill about what dosage to select. As Dr. Steinman testified "there's a precision definition that focuses on making the drug available to a person who, for instance, might not have immunity to varicella zoster. But nothing was known about the .5 in terms of whether that would be the right way to do it in the public domain." (*Id.* at 23:16–24:12.)

Defendants' reliance on *Novartis Pharms. Corp. v. W.-Ward Pharms. Int'l Ltd.*, 923 F.3d 1051 (Fed. Cir. 2019), is off-point. In *Novartis*, the Federal Circuit found that the District Court improperly applied a lead compound analysis to a method claim that did not claim the chemical compound and had nothing to do with selecting a dosage for use in a claimed method. *Id.* at 1060 (holding "[t]his case therefore does not require [a] lead compound analysis" requiring the defendant to show that by clear and convincing evidence that everolimus itself would have been selected over other prior art compounds). The '179 Patent is a method of treatment patent, which requires that Defendants show a motivation for the person of skill to select the claimed dosage from the prior art. *See, e.g., Janssen Pharms., Inc. v. Mylan Laby's Ltd.*, 2025 WL 946390, at *4 (Fed. Cir. 2025) (upholding district court's finding that, despite the existence of prior art describing a PP1M dosing regimen, the prior art would not have motivated a skilled artisan to use that

regimen). Dr. Steinman's testimony properly rebuts Dr. Pleasure's asserted motivation to select the claimed dosage of 0.5 mg fingolimod in the context of the '179 Patent claims.

C. Dr. Steinman Applied the Correct Standard for Non-Obviousness

Defendants lastly argue that "Dr. Steinman applies an incorrect certainty standard for obviousness." (D.I. 383-0 at 12–14.) Defendants cite excerpts of Dr. Steinman's testimony regarding the data available to a person of skill concerning vaccinating a VZV seronegative patient prior to administering fingolimod. (*Id.* at 13–14.) Yet again, Defendants conspicuously leave out other portions of the testimony in the line of questioning to which they refer.

Contrary to Defendants' claim, Dr. Steinman's opinion is not that clinical certainty was needed. Rather, his opinion is that as of September 2010, there was no public data at all concerning whether fingolimod's mechanism of action would interfere with the vaccine's efficacy in providing protection against VZV after fingolimod treatment was initiated—let alone enough information to give a person of ordinary skill a reason to disregard the potential risks associated with giving a live VZV vaccine to a RRMS patient.

Indeed, Dr. Steinman's testimony regarding clinical data was in response to a question from Defendants' counsel regarding what a person of skill would have needed to know to have a reasonable expectation of success. Dr. Steinman explained that critical data regarding VZV vaccination prior to treatment 0.5 mg of fingolimod was missing from Dr. Pleasure's asserted prior art: "you would need to know what the dose was that was best to immunize if the person was on an immune suppressive drug . . . [t]here's a lot of what-ifs . . . [w]hat if the higher dose gave you a better immunization and yet increased the risk of getting the infection once you got on the drug." (D.I. 393-1, Ex. B (7/18/2025 Steinman Dep. Tr.) at 179:8–180:11; *see also* D.I. 386-1, Ex. S (Steinman Reb. Rpt.) ¶ 237 ("Only after the inventors analyzed the study data was a connection

between the 0.5 mg dose [of fingolimod] and risk of VZV infection revealed").) Such expert testimony is proper where, as here, the absence of relevant pharmacological data in the prior art demonstrates a lack of reasonable expectation of success. *Janssen Pharms.*, 2023 WL 3605733, at *28 ("[S]ince the art lacked PK data about PP3M, a POSA would have had no reason to believe that PP1M would reach therapeutic concentrations faster than PP3M when used for reinitiation.").

II. Defendants Are Not Entitled to Summary Judgment of Invalidity Under § 103

A. The '179 Patent Is Not Invalid as Obvious

Defendants argue that the '179 Patent claims are obvious, largely reiterating the substance of Dr. Pleasure's expert reports. (D.I. 383-0 at 14–25.) Defendants not only fail to put forth clear and convincing evidence of invalidity, but also ask the Court to ignore the overwhelming evidence of non-obviousness comprising Dr. Pleasure's own concessions as well as Dr. Steinman's report and testimony. In any case, several questions of material fact regarding obviousness of the '179 Patent remain, and Defendants' motion for summary judgment must fail.

1. The evidence shows that the claim elements were not in the prior art

Claim 1 preamble. Defendants contend that Dr. Steinman does not dispute that a person of skill would have understood the prior art discloses claim 1 preamble "[a] method for treating relapsing-remitting multiple sclerosis in a patient in need thereof," based on the Kappos NEJM 2010's disclosure that both the 0.5 mg and the 1.25 mg dose of fingolimod were shown to reduce the annualized relapse rate in RRMS patients. (D.I. 383-0 at 15.)

Contrary to Defendants' characterization, a significant factual dispute remains as to whether the claim 1 preamble is disclosed in the prior art, in view of the relevant opinions from Dr. Steinman. In his expert report, Dr. Steinman explained that at least because the prior art does

not disclose "vaccinating the patient at risk of contracting [VZV] infection," the prior art "necessarily failed" to disclose claim 1 "as construed by the Court," which he explained includes a construction that the preamble is a "limiting statement of purpose." (D.I. 386-1, Ex S (Steinman Reb. Rpt.) ¶¶ 214, 176.) In deposition, Dr. Steinman expressly "disagree[d]" that a person of skill would have known of a method for treating RRMS in a patient need thereof. (D.I. 393-1, Ex. B (7/18/2025 Steinman Dep. Tr.) at 16:19–23.)

Dr. Steinman explained that a POSA would have known that "[fingolimod] was being tested at .5, but they also knew that the drug was being tested at 1.25," and "nothing was known about the .5 in terms of whether that would be the right way to [treat an RRMS patient] in the public domain." (*Id.* at 23:16–24:12.) And a POSA reading Cohen 2010 would additionally "need to know all of the things that are necessary to choose a dose, especially in the context of '179, which is a method for protecting people from a consequence that would -- they would want to avoid. So you would need to know a lot more before making that decision." (*Id.* at 42:8–16; *id.* at 43:2–17 ("A POSA only would know what was in [Cohen 2010,] and I don't think that would be sufficient [to determine that it would be obvious to treat an RRMS patient with 0.5 mg daily dose of fingolimod]").)

Claim 1(a). Similarly, Defendants incorrectly argue that Dr. Steinman does not dispute that "Kappos/Cohen + Berger + Harpaz discloses" claim 1(a). (D.I. 383-0 at 15.) Specifically, Defendants contend that a POSA would have been concerned about the clinical trial death and motivated to look for information on fingolimod's VZV risk in the prior art. (*Id.* at 15–16.) Among others, Defendants allege that Berger 2009 "discusses potential management of infection risk in MS patients receiving immunomodulatory drugs," citing the passage stating "[i]f a substantial risk for reactivated varicella zoster exists with some of these treatments, one might

argue that vaccination with the live virus varicella zoster virus vaccine be undertaken before the administration of that particular treatment."[1] (*Id.* at 16 (citing D.I. 393-16, Ex. CCCC (Berger 2009) at 373).) According to Defendants, a person of skill would further find in Harpaz "recommendations" about identifying patients at risk of VZV infection before fingolimod therapy. (*Id.*)

Defendants incorrectly characterize the document in claiming that Harpaz 2008 teaches "ask[ing] the patient 'about their history of varicella (chickenpox) or to have serologic testing conducted to determine varicella immunity.'"[2] (*Id.* at 17.) The full passage reads the opposite, teaching a person of skill ***not*** to identify an at-risk patient: "[b]efore routine administration of zoster vaccine, it is ***not necessary to ask patients*** about their history of varicella (chickenpox) ***or to conduct serologic testing*** for varicella immunity." (D.I. 393-16, Ex. HHHH (Harpaz 2008) at 19 (emphases added).)

Defendants' argument also ignores the Court's claim construction and the evidence in the record to the contrary. Claims 1(a)–(c) must be performed sequentially and for the purpose of treating RRMS. (D.I. 234 at 10.) As Dr. Steinman explains, at the time of Harpaz's publication, fingolimod—the first S1P receptor modulator approved for humans—was not yet available as a therapy, and there was no immunomodulator on the market that worked by sequestering lymphocytes, rather than destroying or impairing them. (D.I. 386-1, Ex. S (Steinman Reb. Rpt.)

[1] This conditional statement does not mean that VZV vaccination of RRMS patients prior to fingolimod therapy would have been obvious. As Dr. Berger himself explained, "[he] deliberately conditioned this statement, because of the numerous unresolved questions that were pending regarding a potential association between VZV and immunomodulatory drugs." (D.I. 386-1, Ex. P (Berger Reply Rpt.) ¶ 12.)

[2] It should be noted that Dr. Pleasure never cited this portion of Harpaz 2008 in his expert reports regarding alleged invalidity of claim 1(a).

¶¶ 219–225.) As such, Harpaz 2008's alleged recommendation does not translate to identifying an at-risk RRMS patient prior to vaccination and fingolimod treatment. As explained below with respect to claim 1(b), nothing else in the prior art discloses vaccinating a VZV seronegative patient for VZV prior to fingolimod therapy. (*Id.* ¶¶ 214–225.)

Claim 1(b). Defendants argue that a POSA would follow Harpaz's disclosure for patients 60 and up "for all persons aged [≥]12 months who lack evidence of immunity." (D.I. 383-0 at 17 (original text in Harpaz 2008 in brackets).) As explained above, Defendants have failed to support this claim with clear and convincing evidence, and a significant factual dispute remains as to whether the prior art discloses claim 1(b).

Pointing to only their reasoning for claim 1(a), Defendants again misconstrue Harpaz 2008's alleged disclosures. Citing the passage providing that zoster vaccination status review should be considered in "patients aged **≥60** years" who might begin immunosuppressive therapy, Defendants incorrectly quote the phrase as "patients aged **<60** years," as if the latter were the original text. (*Contrast* D.I. 383-0 at 18, *to* D.I. 393-16, Ex. HHHH (Harpaz 2008) at 19 (emphases added).) This inaccurate quotation skirts one of many reasons why Harpaz 2008 would not have been applicable, which is that MS onset "usually occurs between the ages of 20 and 40 years." (D.I. 386-1, Ex. S (Steinman Reb. Rpt.) ¶ 26.) Without any other explanation, Defendants also replace the word "zoster" (*i.e.*, secondary VZV reactivation) with "[primary VZV]" to argue that Harpaz 2008's recommendations regarding shingles regarding patients ≥60 years expands to a blanket recommendation for varicella vaccination for the general population. (*Contrast* D.I. 383-0 at 18, *to* D.I. 393-16, Ex. HHHH (Harpaz 2008) at 20.)

As Dr. Steinman explained, with no S1P receptor modulator approved at the time, Harpaz 2008's references to "immunosuppressive therapy" would not be understood to be a reference to

drugs that modulate the immune system through lymphocyte sequestration (as opposed to impairment or destruction) generally, let alone fingolimod specifically. (D.I. 386-1, Ex. S (Steinman Reb. Rpt.) ¶ 221.) More significantly, neither Harpaz 2008 nor any other prior art reference confirmed whether fingolimod is correlated with VZV infection, or whether vaccines would even be effective in fingolimod recipients. (*Id.* ¶ 222.) As such, a person of skill would have found "no suggestion to apply" Harpaz 2008's alleged blanket recommendation regarding "routine varicella vaccination for all persons aged ≥12 months" to RRMS patients prior to fingolimod therapy. (*Id.* ¶¶ 219–225.)

Defendants improperly frame several statements from Dr. Steinman as an acknowledgement of "all facts necessary for obvious [*sic*] to be the only outcome based on correct legal standards." (D.I. 383-0 at 19–24.) Defendants cite Dr. Steinman's testimony that "a POSA would be concerned that fingolimod was at least one of the culprits" of the TRANSFORMS death. (*Id.* (citing D.I. 393-1, Ex. B (7/18/2025 Steinman Dep. Tr.) at 152:11–20).) But that a POSA might have been "concerned" about fingolimod potentially contributing to the TRANSFORMS death does not rise to clear and convincing evidence that the claimed VZV vaccination protocol would have been obvious. As Dr. Steinman explains at length, several questions needed to be investigated before a sufficient risk-benefit profile would justify implementing such a protocol, reflected in the range of differing opinions from the Steering Committee on this issue. Among others, these questions included: (1) whether fingolimod increased VZV infection risk and (2) whether a vaccine would be effective in fingolimod recipients. (D.I. 386-1, Ex. S (Steinman Reb. Rpt.) ¶ 230.)

First, whether fingolimod in fact increased the risk of VZV infection was not known as of September 2010. (D.I. 386-1, Ex. S (Steinman Reb. Rpt.) ¶¶ 219–225; D.I. 393-1, Ex. B

(7/18/2025 Steinman Dep. Tr.) at 120:23–122:5.) Dr. Pleasure expressly admitted this fact. (D.I. 386-1, Ex. K (7/14/2025 Pleasure Dep. Tr.) at 219:18–220:1 ("Sitting here today, I don't recall any [study before September 2010 linking the use of fingolimod to an increased risk of VZV infection]."), 221:6–223:10 ("However, I do not believe that there were any publications to that effect, as yet.").) That study was conducted internally by Novartis scientists including Dr. de Vera, the results of which were not published until 2015. (Ex. 1 (Arvin 2015); D.I. 386-1, Ex. S (Steinman Reb. Rpt.) ¶¶ 136–143, 214–225; *see also*, *e.g.*, D.I. 393-1, Ex. B (7/18/2025 Steinman Dep. Tr.) at 96:20–97:19, 119:13–122:5.)

Second, Defendants also do not contest the additional confounding factors that the TRANSFORMS subject was receiving a higher-than-claimed 1.25 mg dose of fingolimod and high-dose corticosteroids. (D.I. 393-1, Ex. B (7/18/2025 Steinman Dep. Tr.) 76:4–18.) As Dr. Pleasure admitted, "[c]orticosteroid alone can be a risk factor" for VZV infection. (D.I. 386-1, Ex. K (7/14/2025 Pleasure Dep. Tr.) at 192:23–25.) For that reason, contemporary publications reporting the TRANSFORMS death—including Cohen 2010, Berger 2009, and Garber 2008—explicitly recognized that the concomitant use of a high dose of corticosteroids made it impossible to conclude that fingolimod was a contributing factor. (D.I. 386-1, Ex. S (Steinman Reb. Rpt.) ¶¶ 223, 228, 237; D.I. 393-1, Ex. B (7/18/2025 Steinman Dep. Tr.) at 136:18–137:23 ("I've stated throughout the report that both Berger 2009 and Garber [2008] reporting in Nature Biotechnology mentioned that the patient's concomitant use of a high dose of steroids made it impossible to conclude that fingolimod was a contributing factor to the patient's infection or death."), 193:6–10 ("Q. And by 'with confounds,' you mean with the coadministration of high doses of corticosteroids? A. That's right. And just more than the coadministration. The self-administration of other doses of corticosteroids.").)

Third, whether fingolimod recipients would mount a sufficient vaccine response was also not known as of September 2010. Berger 2009 explicitly notes that the cause of the TRANSFORMS death may be due to corticosteroid treatment, and additionally warns that "the safety of vaccination in the setting of these immunomodulatory drugs needs to be established" and "an attenuated response to certain vaccines may be observed in this MS population." (D.I. 393-16, Ex. CCCC (Berger 2009) at 373; D.I. 386-1, Ex. S (Steinman Reb. Rpt.) ¶ 223.) The D2109 clinical study, which simulated antigenic responses both in terms of T-cell mediated and humoral immunity mechanisms in fingolimod recipients, was also conducted internally and not published until 2012. (Ex. 2 (Boulton 2012); D.I. 386-1, Ex. S (Steinman Reb. Rpt.) ¶¶ 144–149.) Dr. Pleasure admitted that he is "unaware" of any prior art study evaluating 0.5 mg fingolimod recipients' ability to maintain T-cell and humoral antibody responses. (D.I. 386-1, Ex. K (7/14/2025 Pleasure Dep. Tr.) at 253:21–254:11.)

2. Defendants ignore the affirmative evidence of non-obviousness

While correctly acknowledging that Dr. Steinman "identified reasons that a POSA may not have wanted to vaccinate a patient prior to receiving fingolimod," Defendants nonetheless ask that the Court also ignore the affirmative evidence of non-obviousness. (D.I. 383-0 at 21.) The prior art taught away from the claims, at least based on the neurological community's long-held caution against administering live vaccines to MS patients for fear of infection and triggering relapses. (D.I. 386-1, Ex. S (Steinman Reb. Rpt.) ¶ 227.) Live vaccines could itself induce an infection in susceptible individuals. (*Id.* ¶ 240.) From the mid-20th century, viral infections were linked to an increased risk of MS relapses. (*Id.* ¶¶ 38–42, 239.) VZV specifically was correlated with both MS onset and MS relapses, demonstrated by multiple studies showing VZV DNA fragments in the spinal fluid during relapses. (*Id.* ¶¶ 43–46, 240.)

But that does not mean it was certain whether VZV "caused MS" or "trigger[ed] relapses" as Defendants suggest. (D.I. 383-0 at 21.) Rather, without a good reason to do so (*i.e.*, Novartis's analysis of the dose-dependent VZV risk and the D2109 study[3]), a person of skill would have been hesitant to administer a VZV vaccine to an MS patient prior to fingolimod therapy. This is consistent with the doubts expressed in the "diversity of opinion" from the Steering Committee members on the issue of vaccinating VZV seronegative MS patients, which Dr. Steinman testified demonstrates non-obviousness. (D.I. 386-1, Ex. S (Steinman Reb. Rpt.) ¶¶ 120–123, 231; *see, e.g.*, D.I. 393-1, Ex. B (7/18/2025 Steinman Dep. Tr.) at 56:9–18.)

Defendants also misstate paragraph 142 of Dr. Steinman's report, to somehow frame it as an admission that "a POSA would have had a reasonable expectation of success for this vaccination." (D.I. 383-0 at 23.) Novartis's risk-benefit analysis was not known in 2010; the "enough information" supporting a "theoretical" benefit to both herpes zoster and chickenpox refers to the known overlap between their molecular pathology in terms of humoral and cell-mediated antibody response. (D.I. 386-1, Ex. S (Steinman Reb. Rpt.) ¶¶ 140–143.)

Given the extensive opinion and testimony from Dr. Steinman, a factual issue remains as to whether claim 1(b) is obvious.

Claim 1(c). For the reasons stated above, a factual issue remains as to claim 1(c)'s alleged obviousness, in view of the Court's construction that administering 0.5 mg fingolimod orally must occur after the vaccination step 1(b).

Given the genuine issues of material fact regarding at least claims 1(a)–(c) explained above, Defendants' summary judgment motion must be denied.

[3] Nothing about Dr. Steinman's analysis requires "certainty and clinical data" regarding these investigations. To the contrary, these endeavors by Novartis demonstrates that a POSA would not have had enough information in the prior art to arrive at the claims.

Secondary considerations. Relying only on conclusive statements that the '179 Patent is "not novel" and that the asserted claims "do not drive the marketplace performance of Gilenya," Defendants argue that there is no factual dispute regarding secondary considerations. But Defendants do not challenge any evidence Dr. Steinman analyzed with respect to copying and commercial success (D.I. 386-1, Ex. S (Steinman Reb. Rpt.) ¶¶ 250–256), nor did they ask about either issue in his deposition. Thus, it is Defendants who concede that the secondary considerations weigh against finding obviousness.

CONCLUSION

For the foregoing reasons, the Court should deny both Defendants' *Daubert* motion to preclude Dr. Steinman's testimony and their motion for summary judgment of invalidity under 35 § U.S.C. 103.

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CERTIFICATE OF SERVICE

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